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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,078	04/25/2001	Olivier De Lacharriere	016800-438	6852

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EXAMINER	
WELLS, LAUREN Q	
ART UNIT	**PAPER NUMBER**
1617	17

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,078	LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20 and 23-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20 and 23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/580,291.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 19-20, 23-37 are pending. The Amendment filed 10/16/03, Paper No. 16, cancelled claims 1-16 and 21-22.

The Finality of the Office Action mailed 7/16/03, is hereby withdrawn, for the reasons of the below rejection. The instant action is a non-final Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-20, 23-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for auranofin, SKF-105809 and lactoferin as the interleukin 1 antagonist and enabling for lisophyline, A802715 and sulphasalazine as the TNF alpha antagonist, does not reasonably provide enablement for any interleukin 1 antagonist or any TNF alpha antagonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides a composition comprising an amount of TNF alpha antagonist sufficient to eliminate or alleviate an irritant side effect, an acceptable medium, and an agent

selected from alpha-keto acids, beta-keto acids, retinoids, anthralins, antrhranoids, peroxides, minoxidil, lithium salts, antimetabolites, vitamin D and depigmentation agents.

(2) The state of the prior art

The prior art does not teach interleukin 1 or TNF alpha antagonists in cosmetic embodiments.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the cosmetic art containing cell antagonists is very high, as it is impossible to predict the molecular pathway through which an antagonist will work to produce a physiological effect, especially since each agonist has a chemically distinct structure and hence, affects the cell and the resulting physiological effect in a unique manner.

(5) The breadth of the claims

The claims are very broad. TNF alpha antagonists and interleukin 1 antagonists encompass a broad range of compounds that are chemically distinct, with no common structure. An antagonist can range from a peptide to a heterocylic compound to a salt to many other organic and inorganic compounds.

(6) The amount of direction or guidance presented

The specification on page 9, [0035]-[0037], teaches that the interleukin 1 release antagonist can be auranofin, SKF 105809, or lactoferin, and that the TNF-alpha receptor antagonist can be lisophilyine, A802715, or sulphasalazine. However, the specification does not provide any other direction or guidance as to what other antagonists can be utilized in the instant invention. And the compounds recited on pages 9 have vastly different chemical structures. Auranofin is a six-membered carbon ring containing an oxygen heteroatom and side chains ranges from –OAc, to –CH2OAc, to –S-Au-PEt3. SKF 105809 is 6,7-dihydro-2-[4-(methylsulfinyl)phenyl]-3-(4-pyridinyl)-5H-pyrrolo[1,2-a]imidazole. Lactoferin is a glycoprotein. Lisophyline is a bicyclic compound, wherein the rings are attached, and one ring is 5-membered comprising two nitrogen atoms and 3 carbon atoms, and the other ring is six-member comprising two nitrogen atoms and 5 carbon atoms, wherein two carbonyl groups are attached to the ring, as is a side chain. Sulphasalazine is a compound containing three rings, wherein the rings are six member and contain three double bonds, wherein one of the rings contains a nitrogen heteroatom, and the rings are attached by nitrogen and sulfate atoms.

The Examiner respectfully points out that In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure

should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

While the instant specification does provide working examples, the examples are limited to the specific antagonists recited on page 9 of the specification. Furthermore, it is noted that not all of the examples contain an interleukin 1 receptor antagonist or a TNF-alpha receptor antagonist.

(8) The quantity of experimentation necessary

Since the significance of particular chemical compounds or peptides for different aspects of biological activity on interleukin and TNF cells cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the all of the chemical compounds and peptides that would antagonize interleukin and TNF cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

11/20/05